UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF MICHIGAN

GARY KRUEGER and
VIRGINIA KRUEGER

Plaintiffs

v.

HON.

CASE NO.:

NEW ENGLAND COMPOUNDING PHARMACY, INC. a/k/a NEW ENGLAND COMPOUNDING CENTER

Defendant.

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TERRY A. DAWES (P47854)
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COMPLAINT & DEMAND FOR JURY TRIAL

NOW COME Plaintiffs, GARY KRUEGER and VIRGINIA KRUEGER, by and through their attorneys FIEGER, FIEGER, KENNEY, GIROUX & DANZIG, PC and for their Complaint allege that at all times relevant:

1. This lawsuit is being filed by Gary Krueger and Virginia Krueger.

2. Plaintiffs are residents of Wayne County in the State of Michigan.

3. Defendant, New England Compounding Pharmacy, Inc., a/k/a New England Compounding Center (NECC) is incorporated under the laws of the State of Massachusetts.

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4. This lawsuit arises out of a multistate outbreak of fungal infections among patients who received contaminated methylprednisolone acetate (MPA) that was manufactured and distributed by defendant. Gary Krueger received a contaminated injection of MPA manufactured by NECC and contracted fungal infection due to the introduction of fungus, mold and other contaminants into his body. He was hospitalized as a result of being injected with the contaminated drug.

5. The amount in controversy in this case greatly exceeds the statutory amount of $75,000.00.

6. Complete diversity exists between the parties; therefore, jurisdiction is proper pursuant to 28 USC 1332.

FACTUAL ALLEGATIONS

7. On or about September 26, 2012, Gary Krueger visited Michigan Pain Specialists located in Brighton, Michigan.

8. At that time, he was administered an injection of contaminated MPA manufactured by NECC for pain management purposes.

9. Shortly thereafter, he became ill.

10. Nationwide, multiple cases of fungal meningitis, fungal infected joints and deaths, have been reported to be caused by MPA compounded by NECC.

11. The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) are coordinating a multi-state investigation of the meningitis outbreak, and CDC reports that interim data show that all infected patients received an with preservative-free MPA (80mg/ml) prepared by NECC,

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located in Framingham, MA. See < http://www.nabp.net/news/outbreak-of-meningitis-associated-with-contaminated-intrathecal-steroid-/>.

12. According to the CDC, there is multiple reported cases of fungal meningitis cases in Michigan and reported deaths, as of the filing of this complaint. See http://www.cdc.gov/hai/outbreaks/meningitis-map.html.

13. Nationwide, there have been numerous fungal meningitis cases and deaths linked to the contaminated MPA manufactured and distributed by NECC, as of the filing of this complaint. See http://www.cdc.gov/hai/outbreaks/meningitis-map.html.

14. Defendant is engaged in the business of manufacturing medications, including MPA.

15. Defendant manufactured MPA that was contaminated with fungus, mold and other contaminants.

16. Defendant is not accredited by the Pharmacy Compounding Accreditation Board (PCAB).

17. On information and belief, Defendant has previously designed, manufactured, marketed, sold and distributed contaminated MPA which caused at least one death.

18. On information and belief at least three lots of contaminated MPA were designed, manufactured, marketed, sold and distributed by Defendant NECC specifically: Lot #05212012@68, Lot #06292012@26 and Lot #08102912@51.

19. Defendant allowed medications contaminated with fungus, mold and other contaminants to be marketed, sold and distributed into the stream of commerce throughout the United States including the State of Michigan.

20. As a direct and proximate result of being administered MPA made by Defendant which was contaminated with fungus, mold and other contaminants Gary Krueger developed fungal infection and related sequellae.

21. As a direct and proximate result of being administered MPA made by Defendant which was contaminated with fungus, mold and other contaminants, Gary Krueger sustained compensable injuries and damages.

22. As a direct and proximate result of Gary Krueger being administered MPA made by Defendant which was contaminated with fungus, mold and other contaminants, Virginia Krueger sustained a compensable loss of consortium.

COUNT I: STRICT LIABILITY

23. Plaintiffs incorporate by reference paragraphs 1 through 22.

24. Defendant was engaged in the development, testing, manufacturing, marketing and sales of MPA.

25. Defendant designed, manufactured, marketed and sold the MPA to medical professionals knowing it would be injected into patients.

26. The MPA was designed, manufactured, marketed and sold by Defendant, reached Gary Krueger without substantial change in its condition and was used by him in a reasonably foreseeable and intended manner.

27. The MPA was defective and unreasonably dangerous when it entered the stream of commerce and was received by Gary Krueger because it

was dangerous to an extent beyond that which would be contemplated by the ordinary consumer.

28. At no time did Gary Krueger have reason to believe that the MPA was in a condition not suitable for its proper and intended use among patients.

29. The MPA was used in the manner for which it was intended which resulted in injury and damages to Gary Krueger.

30. The MPA was defective due to defective design rendering the product unsafe.

31. The MPA was not reasonably safe due to defective design, because the foreseeable risks of harm posed by the product were sufficiently greater than its foreseeable therapeutic benefits, such that reasonable health providers knowing of the foreseeable risks and lack of therapeutic benefits would not prescribe the product for any class of patients.

32. Gary Krueger was not able to discover through the exercise of reasonable care, the defective nature of the MPA.

33. Gary Krueger neither new nor through the exercise of reasonable care could have known that Defendant had designed, developed, and manufactured the MPA in such a way as to make the risk of harm or injury outweigh any therapeutic benefits.

34. The MPA was defective in design because of the contamination that has the propensity to cause patients to become ill.

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35. The MPA is defective in design because the increased risk for illness is unreasonably greater than other MPA. The product offers no clinical benefit over other MPA that compensates in whole or in part for the increased risk.

36. The MPA was unreasonably dangerous because it was sold to Gary Krueger without adequate warnings regarding the propensity of the MPA to cause illness, the post-marketing experience of higher rates of illness and the probability of suffering illness.

37. Defendant failed to develop and make available alternative products that were designed in a safe or safer manner, even though such products were feasible and marketable at the time Defendant sold the MPA to Gary Krueger.

38. Defendant knew or should have known of the defective and dangerous nature of the MPA.

39. Despite the fact that Defendant knew or should have known, Defendant failed to adequately and sufficiently warn Gary Krueger or his health providers that the MPA was likely to cause permanent injuries and damages including but not limited to death.

40. As a direct and proximate result of the Defendant's wrongful conduct, including but not limited to defective and dangerous design and inadequate warnings of the MPA, Plaintiffs have sustained and will continue to sustain severe and debilitating injuries and damages of an economic and non economic nature including but not limited to illness, medical and prescription expenses, lost earnings, lost earnings capacity, physical and emotional pain and suffering for

which they are entitled to compensatory and exemplary damages which will be proven at trial.

41. Defendant's conduct was reckless; Defendant risked the lives of consumers and users of their product, including Gary Krueger's, with knowledge of the safety and efficacy problems and failed to disclose this information to the public.

42. Defendant made conscious decisions not to re-design, re-label, warn or inform the unsuspecting public; therefore, its conduct warrants an award of exemplary damages.

WHEREFORE, Plaintiffs demand judgment against Defendant for compensatory and exemplary damages plus all allowable interest, costs, attorney fees and any other relief deemed just by the court.

COUNT II: STRICT LIABILITY-FAILURE TO WARN

43. Plaintiffs incorporate by reference paragraphs 1 through 42.

44. Defendant researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce the MPA then advertised or marketed the product to health providers and consumers including Gary Krueger or persons responsible for consumers and therefore had a duty to warn of the risks associated with the use of the MPA.

45. Defendant failed to adequately warn health professionals and the public, including Gary Krueger and his prescribing physician, of the true risks of the MPA including that the product could cause illness.

46. Defendant failed to timely and properly warn of materials facts regarding the safety and efficacy of the MPA. Proper warnings would have been heeded and no health provider including Gary Krueger's would have used the MPA and no consumer including Gary Krueger would have used the MPA.

47. Defendant failed to timely and properly provide adequate instructions and training concerning safe and effective use of the MPA. Adequate instructions and training concerning safe and effective use of the MPA would have prevented all claimed injuries and damages because the product would not have been used.

48. The MPA which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendant, was defective due to inadequate post-marketing warnings and/or instruction because after Defendant knew of should have known that there was reasonable evidence of an association between the MPA and illness, Defendant failed to provide adequate warnings to health professionals and the consuming public, including Gary Krueger and continued to aggressively promote the MPA.

49. The MPA was defective due to inadequate postmarketing warnings and/or instruction regarding increased risk of illness while knowing that a safer design existed.

50. Defendant failed to provide adequate warnings to health professionals and the consuming public, including Gary Krueger, and continued to aggressively promote the MPA even though they provide no clinical benefits over other MPA and had a higher risk of illness.

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51. Defendant failed to perform or otherwise facilitate adequate testing; failed to and/or concealed testing and research data and selectively and misleadingly revealed and/or analyzed testing and research data.

52. As a direct and proximate result of the conduct of Defendant, Plaintiffs suffered serious and permanent injuries and damages of an economic and non-economic type.

53. Defendant's conduct was reckless; Defendant knowingly risked the lives of consumers and users of their products, including Gary Krueger's and made conscious decisions not to re-design, re-label, warn or inform the unsuspecting public. Defendant's reckless conduct warrants an award of exemplary damages.

WHEREFORE, Plaintiffs demand judgment against Defendant for compensatory and exemplary damages plus all allowable interest, costs, attorney fees and any other relief deemed just by the court.

COUNT III: STRICT LIABILITY-MANUFACTURING DEFECT

54. Plaintiffs incorporate by reference paragraphs 1 through 53.

55. Defendant designed, developed, manufactured, tested, packaged, advertised, promoted, marketed, distributed, labeled and/or sold MPA, in a condition which rendered them unreasonably dangerous due to its propensity to cause illness. The MPA was unreasonably dangerous in construction or composition.

56. The MPA was defective when it left Defendant's custody and control and deviated in a material and significant way from Defendant's manufacturing

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performance standards and/or it differed from otherwise identical products manufactured to the same design formula. Defendant knew or should have known that it was reasonably foreseeable that the MPA could cause injuries and damages to patients who received it. Despite this, Defendant continued to market the MPA as a safe and effective product.

57. As a direct and proximate result of the use of the product Plaintiffs suffered compensable injuries and damages of an economic and non-economic nature.

WHEREFORE, Plaintiffs demand judgment against Defendant for compensatory and exemplary damages plus all allowable interest, costs, attorney fees and any other relief deemed just by the court.

COUNT IV: NEGLIGENCE & GROSS NEGLIGENCE

58. Plaintiffs incorporate by reference paragraphs 1 through 57.

59. Defendant owed a duty to Plaintiffs and to the public in general to timely and properly:

a. Design, manufacture, test , inspect and sell MPA that is reasonably safe and fit for intended purpose,
b. Establish quality control measures,
c. Implement quality control measures,
d. Manufacture uncontaminated products ,
e. Quality test its products for contamination prior to releasing the products into the stream of commerce,
f. Identify contaminated products prior to releasing the products into the stream of commerce,
g. Refrain from releasing contaminated products into the stream of commerce,

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h. Warn the public and health providers of the risk of contamination

i. Use alternative production practices that would have prevented the contamination, and

j. Any other act or omission determined during the course of discovery.

60. Defendant breached these duties by failing to timely and properly:

a. Design, manufacture, test, inspect and sell MPA that are reasonably safe and fit for intended purpose,

b. Establish quality control measures,

c. Implement quality control measures,

d. Manufacture uncontaminated products ,

e. Quality test its products for contamination prior to releasing the products into the stream of commerce,

f. Identify contaminated products prior to releasing the products into the stream of commerce,

g. Refrain from releasing contaminated products into the stream of commerce,

h. Warn the public and health providers of the risk of contamination

i. Use alternative production practices that would have prevented the contamination, and

j. Any other act or omission determined during the course of discovery.

61. The MPA administered to Gary Krueger was not reasonably safe at the time it left the control of Defendant.

62. At the time the product left the control of Defendant, a technically feasible alternative production practice was available that would have prevented the harm without significantly impairing the usefulness or desirability of the product to users and without creating equal or greater risk of harm to others.

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63. Defendant knew or should have known that its design, production, testing and inspecting procedures were substandard and created a foreseeable risk of injury and damage to patients who received their products.

64. Defendant knew or should have known that the MPA was or likely contaminated and use of the product in patients created a reasonably foreseeable risk of injury and damages.

65. Defendant's acts and omissions constitute negligence which is a proximate cause of all injuries and damages claimed by Plaintiffs.

66. Defendant's acts and omissions constitute gross negligence which is a proximate cause of all injuries and damages claimed by Plaintiffs.

67. These breaches of duty proximately caused compensable past, present, and future economic and noneconomic damages to Plaintiffs including but not limited to:

a. Pain and suffering,
b. Disability,
c. Loss of enjoyment of life,
d. Medical and related expenses,
e. Loss of earnings,
f. Aggravation of pre-existing conditions,
g. Loss of consortium, and
h. Any other injury or damage determined during discovery.

WHEREFORE, Plaintiffs demand judgment against Defendant for compensatory and exemplary damages plus all allowable interest, costs, attorney fees and any other relief deemed just by the court.

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COUNT V: NEGLIGENT MISREPRESENTATION

68. Plaintiffs incorporate by reference paragraphs 1 through 67.

69. Prior to Gary Krueger receiving the MPA, Defendant misrepresented that the product was safe and fit for its intended purpose.

70. Defendant failed to disclose material facts regarding the safety of the MPA including information about increased risk of contamination and illness related to contamination.

71. Defendant had a duty to disclose true accurate information and warnings of known and foreseeable dangers of the products they designed, manufactured, marketed and sold.

72. Defendant knew or should have known that their representations of safety and fitness for intended purpose were false and they had a duty to disclose the dangers associated with the product.

73. Defendant made the representations and failed to disclose the materials facts with the intent to induce consumers, including Gary Krueger, and the medical community to act in reliance by purchasing the MPA.

74. Gary Krueger and the medical community justifiably relied on Defendant's representations.

75. Defendant's representations and nondisclosures regarding the safety, purity, and fitness for use was the direct and proximate cause of Plaintiffs' injuries and damages.

76. Defendant's conduct was reckless and warrants an award of exemplary damages.

WHEREFORE, Plaintiffs demand judgment against Defendant for compensatory and exemplary damages plus all allowable interest, costs, attorney fees and any other relief deemed just by the court.

COUNT VI: BREACH OF EXPRESS/IMPLIED WARRANTY

77. Plaintiffs incorporate by reference paragraphs 1 through 76.

78. At all times, Defendant was responsible for manufacturing and processing the MPA at issue, which included the following:

a. Ensuring that the MPA was reasonably fit for its intended use;

b. Inspecting the MPA while it was being manufactured;

c. Testing the MPA to ensure that it was reasonably fit for intended use;

d. Performing an analysis of the MPA;

e. Independently verifying the safety and purity of the MPA;

f. Making representations to Michigan Pain Specialists and other medical health facilities that the batch of MPA was reasonably fit for its intended use.

79. At all relevant times during the design and manufacturing processes, defendant breached express and implied warranties, failed to act reasonably, and caused the batch of MPA to be designed and manufactured in a dangerous and defective condition in one or more of the following ways:

a. The MPA was not reasonably fit for its intended use;

b. The MPA was defective due to a contamination of fungus, mold and other contaminants;

c. The MPA was defective due to inadequate warnings and instructions regarding defects in the materials;

d. By failing to inspect the MPA to make certain that it met express and implied warranties;

e. By failing to test the MPA to make certain that it was not contaminated or dangerous;

f. By manufacturing the MPA in an unreasonably dangerous and defective condition;

g. By failing to otherwise act reasonably.

80. As the direct and proximate result of the breach of express and implied warranties, plaintiffs suffered injuries and damages including, but not limited to the following:

a. Pain and suffering,
b. Disability,
c. Loss of enjoyment of life,
d. Medical and related expenses,
e. Loss of earnings,
f. Aggravation of pre-existing conditions,
g. Loss of consortium, and
h. Any other injury or damage determined during discovery.

WHEREFORE, Plaintiffs demand judgment against Defendant for compensatory and exemplary damages plus all allowable interest, costs, attorney fees and any other relief deemed just by the court.

COUNT VII: VIOLATION OF THE MICHIGAN CONSUMER PROTECTION ACT (MCPA) MCL 445.903

81. Plaintiffs incorporate by reference paragraphs 1 through 80.

82. Defendant was conducting trade or business within the meaning of the MCPA.

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83. Defendant's conduct is not a regulated business or activity; therefore, Defendant is not exempt and the provisions of the MCPA apply.

84. Defendant was engaged in unfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce as defined by MCPA in one of more of the following ways:

a. Causing a probability of confusion or misunderstanding as to the source, sponsorship, approval, or certification of goods;

b. Representing that goods have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have;

c. Representing that goods are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another;

d. Failing to reveal a material fact, the omission of which tends to mislead or deceive the consumer, and which fact could not reasonably be known by the consumer;

e. Failing to provide the promised benefits of the transaction;

f. Making a representation of fact or statement of fact material to the transaction such that a person reasonably believes the represented or suggested state of affairs to be other than it actually is;

g. Failing to reveal facts that are material to the transaction in light of representations of fact made in a positive manner;

h. Any other violations revealed in discovery.

85. As a direct and proximate result of the violations of the MPA Plaintiffs have sustained compensable losses under the act.

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WHEREFORE, Plaintiffs demand judgment against Defendant for compensatory and exemplary damages plus all allowable interest, costs, attorney fees and any other relief deemed just by the court.

COUNT VIII: UNJUST ENRICHMENT

86. Plaintiffs incorporate by reference paragraphs 1 through 85 as though fully set forth herein verbatim.

87. As an intended and expected result of their wrongdoing in the design, manufacture, testing, marketing and selling of contaminated MPA, Defendant has profited and benefited by accepting and retaining payments for contaminated MPA.

88. Gary Krueger expected the MPA was safe and fit for its intended purpose which it was not.

89. Gary Krueger was exposed to and did contract an illness due to the presence of fungal or other contaminants in the MPA which requires extensive expenses for medical and prescription goods and services.

90. The failure of Defendant to provide contaminant free MPA resulted in unjust enrichment of Defendant.

91. Plaintiffs are entitled to equity and seek restitution of Defendant's wrongfully obtained profits, revenues and benefits to the extent and in the amount deemed appropriate by the Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendant for compensatory and exemplary damages plus all allowable interest, costs, attorney fees and any other relief deemed just by the court.

Respectfully submitted,

Fieger, Fieger, Kenney, Giroux & Danzig, P.C.

By: /s/ Terry A. Dawes

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Dated: November 29, 2012

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JURY DEMAND

NOW COME Plaintiffs by and through their attorneys FIEGER, FIEGER, KENNEY, GIROUX & DANZIG, PC and hereby demand a jury trial.

Respectfully submitted,

Fieger, Fieger, Kenney, Giroux & Danzig, P.C.

By: /s/ Terry A. Dawes
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Dated: November 29, 2012